General

Guideline Title

The diagnosis and management of non-alcoholic fatty liver disease: practice guideline by the American Association for the Study of Liver Diseases, American College of Gastroenterology, and the American Gastroenterological Association.

Bibliographic Source(s)

Chalasani N, Younossi Z, Lavine JE, Diehl AM, Brunt EM, Cusi K, Charlton M, Sanyal AJ. The diagnosis and management of non-alcoholic fatty liver disease: practice guideline by the American Association for the Study of Liver Diseases, American College of Gastroenterology, and the American Gastroenterological Association. Hepatology. 2012 Jun;55(6):2005-23. [198 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Gastroenterological Association medical position statement: nonalcoholic fatty liver disease. Gastroenterology 2002 Nov;123(5):1702-4. [3 references]

According to the guideline developer, the Clinical Practice Committee meets three times a year to review all American Gastroenterological Association Institute (AGAI) guidelines. This review includes new literature searches of electronic databases followed by expert committee review of new evidence that has emerged since the original publication date.

Recommendations

Major Recommendations

The grading system for the class of recommendations (1-2) and the levels of evidence (A–C) is defined at the end of the "Major Recommendations" field.

Definitions

The definition of nonalcoholic fatty liver disease (NAFLD) requires that (a) there is evidence of hepatic steatosis, either by imaging or by histology and (b) there are no causes for secondary hepatic fat accumulation such as significant alcohol consumption, use of steatogenic medication or hereditary disorders (see Table 2 in the original guideline document). In the majority of patients, NAFLD is associated with metabolic risk factors such as obesity, diabetes mellitus, and dyslipidemia. NAFLD is histologically further categorized into nonalcoholic fatty liver (NAFL) and nonalcoholic steatohepatitis (NASH) (see Table 3 in the original guideline document). NAFL is defined as the presence of hepatic steatosis with no evidence of hepatocellular injury in the form of ballooning of the hepatocytes. NASH is defined as the presence of hepatic steatosis and inflammation with hepatocyte injury (ballooning) with or without fibrosis.

Alcohol Consumption & Definition of NAFLD

1. Ongoing or recent alcohol consumption >21 drinks on average per week in men and >14 drinks on average per week in women is a reasonable definition for significant alcohol consumption when evaluating patients with suspected NAFLD in clinical practice. (Strength – 2, Quality – C)

Evaluation of Incidentally Discovered Hepatic Steatosis

2. When patients with unsuspected hepatic steatosis detected on imaging have symptoms or signs attributable to liver disease or have abnormal liver biochemistries, they should be evaluated as though they have suspected NAFLD and worked-up accordingly. (Strength – 1, Evidence – A)
3. In patients with unsuspected hepatic steatosis detected on imaging who lack any liver-related symptoms or signs and have normal liver biochemistries, it is reasonable to assess for metabolic risk factors (e.g., obesity, glucose intolerance, dyslipidemia) and alternate causes for hepatic steatosis such as significant alcohol consumption or medications. (Strength – 1, Evidence – A)
4. In patients with unsuspected hepatic steatosis detected on imaging who are asymptomatic and have normal liver biochemistries, a liver biopsy cannot be recommended. (Strength – 1, Evidence – B)

Screening in Primary Care, Diabetes, and Obesity Clinics

5. Screening for NAFLD in adults attending primary care clinics or high-risk groups attending diabetes or obesity clinics is not advised at this time due to uncertainties surrounding diagnostic tests and treatment options, along with lack of knowledge related to the long-term benefits and cost-effectiveness of screening. (Strength – 1, Evidence – B)

Screening of Family Members

6. Systematic screening of family members for NAFLD is currently not recommended. (Strength – 1, Evidence – B)

Initial Evaluation

7. When evaluating a patient with suspected NAFLD, it is essential to exclude competing etiologies for steatosis and co-existing common chronic liver disease. (Strength – 1, Evidence – A)
8. Persistently high serum ferritin and increased iron saturation, especially in the context of homozygote or heterozygote C282Y hemochromatosis (HFE) mutations may warrant a liver biopsy. (Strength – 1, Evidence – B)
9. High serum titers of autoantibodies in association with other features suggestive of autoimmune liver disease (very high aminotransferases, high globulin) should prompt a more complete work-up for autoimmune liver disease. (Strength – 1, Evidence – B)

Non-Invasive Assessment of Steatohepatitis and Advanced Fibrosis in NAFLD

10. As the metabolic syndrome predicts the presence of steatohepatitis in patients with NAFLD, its presence can be used to target patients for a liver biopsy. (Strength – 1, Evidence – B)
11. NAFLD Fibrosis Score is a clinically useful tool for identifying NAFLD patients with higher likelihood of having bridging fibrosis and/or cirrhosis. (Strength – 1, Evidence – B)
12. Although serum/plasma CK18 is a promising biomarker for identifying steatohepatitis, it is premature to recommend in routine clinical practice. (Strength – 1, Evidence – B)

When to Obtain a Liver Biopsy in Patients with NAFLD?

13. Liver biopsy should be considered in patients with NAFLD who are at increased risk to have steatohepatitis and advanced fibrosis. (Strength – 1, Evidence – B)
14. The presence of metabolic syndrome and the NAFLD Fibrosis Score may be used for identifying patients who are at risk for steatohepatitis and advanced fibrosis. (Strength – 1, Evidence – B)
15. Liver biopsy should be considered in patients with suspected NAFLD in whom competing etiologies for hepatic steatosis and co-existing chronic liver diseases cannot be excluded without a liver biopsy. (Strength – 1, Evidence – B)

<u>Management of Patients with NAFLD</u>

Lifestyle Intervention

16. Weight loss generally reduces hepatic steatosis, achieved either by hypocaloric diet alone or in conjunction with increased physical activity. (Strength – 1, Evidence – A)

17. Loss of at least 3-5% of body weight appears necessary to improve steatosis, but a greater weight loss (up to 10%) may be needed to improve necroinflammation. (Strength – 1, Evidence – B)
18. Exercise alone in adults with NAFLD may reduce hepatic steatosis but its ability to improve other aspects of liver histology remains unknown. (Strength – 1, Evidence – B)

Insulin Sensitizing Agents

Metformin

19. Metformin has no significant effect on liver histology and is not recommended as a specific treatment for liver disease in adults with NASH. (Strength – 1, Evidence – A)

Thiazolidinediones

20. Pioglitazone can be used to treat steatohepatitis in patients with biopsy-proven NASH. However, it should be noted that majority of the patients who participated in clinical trials that investigated pioglitazone for NASH were non-diabetic and that long term safety and efficacy of pioglitazone in patients with NASH is not established. (Strength – 1, Evidence – B)

Vitamin E

21. Vitamin E (alpha-tocopherol) administered at daily dose of 800 IU/day improves liver histology in non-diabetic adults with biopsy-proven NASH and therefore it should be considered as a first-line pharmacotherapy for this patient population. (Strength - 1, Quality – B)
22. Until further data supporting its effectiveness become available, vitamin E is not recommended to treat NASH in diabetic patients, NAFLD without liver biopsy, NASH cirrhosis, or cryptogenic cirrhosis (Strength - 1, Quality – C)

Ursodeoxycholic Acid (UDCA), Omega-3 Fatty Acids, and Miscellaneous Agents

23. UDCA is not recommended for the treatment of NAFLD or NASH. (Strength – 1, Quality – B)
24. It is premature to recommend omega-3 fatty acids for the specific treatment of NAFLD or NASH but they may be considered as the first line agents to treat hypertriglyceridemia in patients with NAFLD. (Strength – 1, Quality – B)

Bariatric Surgery

25. Foregut bariatric surgery is not contraindicated in otherwise eligible obese individuals with NAFLD or NASH (but without established cirrhosis). (Strength – 1, Quality – A)
26. The type, safety, and efficacy of foregut bariatric surgery in otherwise eligible obese individuals with established cirrhosis due to NAFLD are not established. (Strength – 1, Quality – B)
27. It is premature to consider foregut bariatric surgery as an established option to specifically treat NASH. (Strength – 1, Quality – B)

Alcohol Use in Patients with NAFLD and NASH

28. Patients with NAFLD should not consume heavy amounts of alcohol. (Strength – 1, Quality – B)
29. No recommendation can be made with regards to non-heavy consumption of alcohol by individuals with NAFLD. (Strength – 1, Quality – B)

Statin Use in Patients with NAFLD and NASH

30. Given the lack of evidence to show that patients with NAFLD and NASH are at increased risk for serious drug-induced liver injury from statins, statins can be used to treat dyslipidemia in patients with NAFLD and NASH. (Strength – 1, Quality – B)
31. Until randomized controlled trials with histological endpoints prove their efficacy, statins should not be used to specifically treat NASH. (Strength – 1, Quality – B)

NAFLD in Patients with Other Chronic Liver Diseases

32. When steatosis and steatohepatitis are evident in patients with other types of chronic liver disease, it is important to assess for metabolic risk factors and alternate etiologies for hepatic steatosis. (Strength – 1, Quality – B)
33. In patients with other types of chronic liver diseases who have co-existing NAFLD and NASH, there are no data to support the use of vitamin E or pioglitazone to improve the liver disease. (Strength – 1, Quality – B)

Miscellaneous Recommendations Pertinent to Clinical Practice

34. Patients with NASH cirrhosis should be screened for gastroesophageal varices according to the AASLD/American College of Gastroenterology (ACG) practice guidelines. (Strength – 1, Quality – B)
35. Patients with NASH cirrhosis should be considered for hepatocellular carcinoma (HCC) screening according to the AASLD/ACG practice guidelines. (Strength – 1, Quality – B)
36. Current evidence does not support routinely repeating a liver biopsy in patients with NAFL or NASH. (Strength – 2, Quality – C)

Aspects of NAFLD Specific to Children and Adolescents

Diagnosis in Children

37. Children with fatty liver who are very young or not overweight should be tested for monogenic causes of chronic liver disease such as fatty acid oxidation defects, lysosomal storage diseases, and peroxisomal disorders, in addition to those causes considered for adults. (Strength – 2, Quality – C)
38. Low serum titers of autoantibodies are often present in children with NAFLD, but higher titers, particularly in association with higher serum aminotransferases and high globulin should prompt a liver biopsy to evaluate for possible autoimmune hepatitis. (Strength – 2, Quality – B)
39. Due to a paucity of evidence, a formal recommendation cannot be made with regards to screening for NAFLD in overweight and obese children despite a recent expert committee recommendation for biannual screening for liver disease with liver enzyme measurements in this population. (Strength – 1, Quality – B)

When To Obtain a Liver Biopsy for Suspected Pediatric NAFLD?

40. Liver biopsy in children with suspected NAFLD should be performed in those where the diagnosis is unclear, where there is possibility of multiple diagnoses, or before starting therapy with potentially hepatotoxic medications. (Strength – 1, Quality – B)
41. A liver biopsy to establish a diagnosis of NASH should be obtained prior to starting children on pharmacologic therapy for NASH. (Strength – 2, Quality – C)

NAFLD Histology in Children

42. Pathologists interpreting pediatric NAFLD biopsies should recognize the unique pattern frequently found in children to not misidentify pediatric NAFLD. (Strength – 1, Quality – B)

Treatment in Children

43. Intensive lifestyle modification improves aminotransferases and liver histology in children with NAFLD and thus should be the first line of treatment. (Strength – 2, Quality – B)
44. Metformin at 500 mg twice daily offers no benefit to children with NAFLD and thus should not be prescribed. The effect of metformin administered at a higher dose is not known. (Strength – 1, Quality – B)
45. Vitamin E 800 IU/day (RRR-alpha–tocopherol) offers histological benefits to children with biopsy-proven NASH or borderline NASH but confirmatory studies are needed before its use can be recommended in clinical practice (Strength – 1, Quality – B)

Definitions:

Grading of Recommendations, Assessment, Development and Evaluation (GRADE)

Strength of Recommendation	Criteria
Strong [1]	Factors influencing the strength of the recommendation included the quality of the evidence, presumed patient-important outcomes, and cost
Weak [2]	Variability in preferences and values, or more uncertainty. Recommendation is made with less certainty, higher cost or resource consumption
Quality of Evidence	
High [A]	Further research is unlikely to change confidence in the estimate of the clinical effect
Moderate [B]	Further research may change confidence in the estimate of the clinical effect
Low [C]	Further research is very likely to impact confidence on the estimate of clinical effect

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Nonalcoholic fatty liver disease (NAFLD), including nonalcoholic fatty liver (NAFL) and nonalcoholic steatohepatitis (NASH)

Guideline Category

Diagnosis

Evaluation

Management

Prevention

Risk Assessment

Treatment

Clinical Specialty

Family Practice

Gastroenterology

Internal Medicine

Nutrition

Pediatrics

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To suggest preferred approaches to the diagnostic, therapeutic, and preventive aspects of care for non-alcoholic fatty liver disease (NAFLD)

Target Population

- Adults and children who may have risk factors for nonalcoholic fatty liver disease (NAFLD)
- Adults and children with suspected or confirmed nonalcoholic fatty liver disease

Interventions and Practices Considered

Risk Assessment/Diagnosis/Evaluation

1. Assessment of alcohol consumption
2. Assessment of metabolic risk factors for nonalcoholic fatty liver disease (NAFLD)
3. Liver biochemistry
4. Screening for NAFLD in primary care, diabetes, and obesity clinics and screening of family members (considered but not recommended)
5. Excluding competing etiologies for steatosis and co-existing common chronic liver disease
6. Testing for genetic hemochromatosis (mutations in the HFE gene)
7. Measurement of serum ferritin and iron saturation
8. Liver biopsy
9. Work-up for autoimmune liver disease in the presence of high serum titers of autoantibodies
10. Use of the NAFLD Fibrosis Score
11. Screening for gastroesophageal varices and hepatocellular carcinoma (HCC)

Management/Treatment

1. Lifestyle interventions such as weight loss and exercise
2. Metformin (specifically not recommended)
3. Pioglitazone
4. Vitamin E
5. Ursodeoxycholic acid (UDCA)(specifically not recommended)
6. Omega-3 fatty acids
7. Foregut bariatric surgery
8. Restricting alcohol use
9. Statins
10. Special consideration for children with NAFLD

Major Outcomes Considered

- Sensitivities, specificities, risks, and costs associated with diagnostic measures
- Treatment outcomes, including:
    - Histology measures
    - Alanine aminotransferase (ALT) levels
    - Presence and degree of hepatic steatosis
    - Presence and degree of fibrosis
    - Presence and degree of ballooning
    - Presence and degree of inflammation
    - Morbidity
    - Mortality

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The literature review included a search of PubMed and Medline. There was no pre-specified starting point and the search ended in June 2011. No pre-specified inclusion/exclusion criteria were applied. No pre-specified search terms were utilized. The writing group was sub-divided into four subgroups and each subgroup consisted three to four members. Each subgroup was assigned sections of the Practice Guideline and was responsible for performing a comprehensive literature search for its assigned sections. Within each subgroup, members were instructed to crosscheck and verify the completeness of the literature search. The Chair of the writing group has independently performed the literature search for all sections to verify that the literature search was comprehensive and was without any obvious bias.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence*

Quality of Evidence	Criteria
High [A]	Further research is unlikely to change confidence in the estimate of the clinical effect
Moderate [B]	Further research may change confidence in the estimate of the clinical effect
Low [C]	Further research is very likely to impact confidence on the estimate of clinical effect

*Classification used by the Grading of Recommendation Assessment, Development, and Evaluation (GRADE) workgroup with minor modifications.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

These recommendations are based on the following: (1) a formal review and analysis of the recently published world literature on the topic; (2) the American College of Physicians' Manual for Assessing Health Practices and Designing Practice Guidelines; (3) guideline policies of the three societies approving this document; and (4) the experience of the authors and independent reviewers with regards to non-alcoholic fatty liver

disease (NAFLD).

Specific recommendations are evidence-based wherever possible, and when such evidence is not available or inconsistent, recommendations are made based on the consensus opinion of the authors.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendations*

Strength of Recommendation	Criteria
Strong [1]	Factors influencing the strength of the recommendation included the quality of the evidence, presumed patient-important outcomes, and cost
Weak [2]	Variability in preferences and values, or more uncertainty. Recommendation is made with less certainty, higher cost or resource consumption

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Cost Analysis

Published cost analyses were reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

This practice guideline was developed in collaboration with the American Association for the Study of Liver Diseases (AASLD) Practice Guidelines Committee, and was approved by the American College of Gastroenterology (ACG) Practice Parameters Committee, and the American Gastroenterological Association (AGA) Institute Clinical Practice and Quality Management Committee.

Submitted for Governing Board approval by Association for the Study of Liver Diseases (AASLD), American College of Gastroenterology (ACG), and American Gastroenterological Association (AGA) on February 22, 2012.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate diagnosis and management of non-alcoholic fatty liver disease (NAFLD)

Potential Harms

- Liver biopsy remains the gold standard for characterizing liver histology in patients with non-alcoholic fatty liver disease (NAFLD). However, it is expensive and carries some morbidity and very rare mortality risk. Thus, it should be performed in those who would benefit the most from diagnostic, therapeutic guidance, and prognostic perspectives.
- Pioglitazone can be used to treat steatohepatitis in patients with biopsy-proven nonalcoholic steatohepatitis (NASH). However, it should be noted that majority of the patients who participated in clinical trials that investigated pioglitazone for NASH were non-diabetic and that long term safety and efficacy of pioglitazone in patients with NASH is not established. In a recent meta-analysis of 19 trials enrolling a total of 16,390 patients with type 2 diabetes mellitus, pioglitazone treatment was associated with a significant reduction (~18%) in the primary outcome of death, myocardial infarction, or stroke (P=0.005). However, there was also a higher rate of congestive heart failure with pioglitazone (2.3% vs. 1.8% in the control group, P=0.002), so caution must be exercised when considering its use in patients with impaired myocardial function.
- One concern with vitamin E is the controversial issue of whether it increases all-cause mortality. Some meta-analyses have reported an increase in all-cause mortality with high dose vitamin E, but others failed to confirm such an association. A recently published randomized controlled trial showed that vitamin E administered at a dose of 400 IU/day increased the risk of prostate cancer in relatively healthy men (absolute increase of 1.6 per 1,000 person years of vitamin E use).
- Although elevated aminotransferases are not uncommon in patients receiving statins, serious liver injury from statins is rarely seen in clinical practice.
- The decision to perform a liver biopsy in a child to confirm the diagnosis of NAFLD must be weighed against the risks associated with biopsy and the likelihood that the result will impact management.

Qualifying Statements

Qualifying Statements

Intended for use by physicians and allied health professionals, these recommendations suggest preferred approaches to the diagnostic, therapeutic and preventive aspects of care. They are intended to be flexible and adjustable for individual patients.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2002 (revised 2012 Jun)

Guideline Developer(s)

American Association for the Study of Liver Diseases - Nonprofit Research Organization

American College of Gastroenterology - Medical Specialty Society

American Gastroenterological Association Institute - Medical Specialty Society

Source(s) of Funding

American Association for the Study of Liver Diseases (AASLD)

AASLD does not accept corporate support for the development of practice guidelines. However, AASLD gratefully acknowledges the support of Genentech and Merck for providing independent medical education grants for mobile download applications for AASLD practice guidelines.

Guideline Committee

Practice Guidelines Committee

Composition of Group That Authored the Guideline

Primary Authors: Naga Chalasani, MD, FACG; Zobair Younossi, MD, FACG; Joel E. Lavine, MD, PhD; Anna Mae Diehl, MD; Elizabeth M. Brunt, MD; Kenneth Cusi, MD; Michael Charlton, MD; Arun J. Sanyal, MD

Financial Disclosures/Conflicts of Interest

Potential conflict of interest: Naga Chalasani, MD, FACG has received compensation for providing consulting related to non-alcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH) from Amylin, Gilead, Genentech, and Mochida and he has received research support from Amylin, Eli Lilly, Intercept, and Cumberland Pharmaceuticals in the last 3 years. Over the last 3 years, he has received compensation for providing consultation related to drug hepatotoxicity from J & J, Merck, GlaxoSmithKline, Karo Bio, Salix, Advanced Life Sciences, BMS, Teva Pharmaceuticals, Abbott, Biolex, Sanofi-Aventis, and Vertex. Zobair Younossi, MD has received consulting fees from Salix, Tibotec, and Vertex. Anna Mae Diehl, MD has received compensation for providing consulting related to NAFLD from Vertex, Norgine, and Celgene. Elizabeth Brunt, MD has received compensation from Amylin, Pfizer, and Geneva Foundation for NASH consulting. Kenneth Cusi, MD has received compensation from Merck, Daichi-Sankyo, and Roche for providing consulting. Michael Charlton, MD has received compensation from Gilead and Genentech for providing consulting related to NAFLD and NASH. Joel Lavine, MD, PhD has received compensation for providing consultations related to NAFLD from Quark Pharmaceuticals and Synageva BioPharma, and received research support from Raptor Pharmaceuticals, all in the last 3 years. Arun Sanyal, MD has served as an ad hoc advisor to Roche, Takeda, Merck, Astella, Sanofi, Exhalenz, and Immuron. He serves as the global principal investigator (PI) for trials for Exhalenz and Immuron.

Raphael B. Merriman, MD, MRCPI and Benjamin L. Shneider, MD served as primary reviewers for the American Association for the Study of Liver Diseases (AASLD) Practice Guidelines Committee. Dr. Merriman declared no relevant conflicts of interest. Dr. Shneider serves as a scientific consultant with Bristol-Myers Squibb and the advisory board for Ikaria. External review was provided by Jean P. Molleston, MD and Stephen A. Harrison, MD. Dr. Molleston received research support from Schering-Plough and Roche. Dr. Harrison serves as a consultant to Amylin Pharmaceuticals and has received research support from Rottapharm and Mochida.

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Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the American Association for the Study of Liver Diseases Web site .

Print copies: Available from the American Association for the Study of Liver Diseases, 1729 King Street, Suite 200; Alexandria, VA 22314; Phone: 703-299-9766; Web site: www.aasld.org ; e-mail: aasld@aasld.org.

Availability of Companion Documents

This guideline is available as a Personal Digital Assistant (PDA) download via the APPRISOR™ Document Viewer from www.apprisor.com .

Patient Resources

None available

NGC Status

This summary was completed by ECRI on January 14, 2003. It was verified by the guideline developer on February 27, 2003. This NGC summary was updated by ECRI Institute on July 3, 2012.

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